



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No.: DC-0232

Inventors: Hillary D. White

Serial No.: 10/677,673

Filing Date: October 2, 2003

Examiner: Not Yet Assigned

Group Art Unit: Not Yet Assigned

Title: Compositions and Methods for Treatment
of Muscle Pain and Muscle Wasting

I, Jane Massey Licata, Registration No. 32,257,
certify that this correspondence is being deposited
with the U.S. Postal Service as First Class mail in
an envelope addressed to the Commissioner for Patents
P.O. Box 1450, Alexandria, VA 22313-1450

On this date: December 10, 2003

Jane Massey Licata
Jane Massey Licata, Registration No. 32,257

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

INFORMATION DISCLOSURE STATEMENT

Pursuant to 37 C.F.R. §1.56 and in accordance with 37 C.F.R. §§1.97-1.98, information relating to the above-identified application is hereby disclosed. Inclusion of information in this statement is not to be construed as an admission that this information is material as that term is defined in 37 C.F.R. §1.56(b).

(XX) In accordance with §1.97(b), since this Information Disclosure Statement is being filed either within three months of the filing date of the above-identified

application, within three months of the date of entry into the national stage of the above identified application as set forth in §1.491, or before the mailing date of a first Office Action on the merits of the above-identified application, no additional fee is required.

- () In accordance with §1.97(c), this Information Disclosure Statement is being filed after the period set forth in §1.97(b) above but before the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311, therefore:

- () Certification in Accordance with §1.97(e) is attached hereto; or

- () The fee of \$180.00 as set forth in §1.17(p) is attached.

- () In accordance with §1.97(d), this Information Disclosure Statement is being filed after the mailing date of either a Final Action under §1.113 or a Notice of Allowance under §1.311 but before the payment of the Issue Fee, therefore included are: Certification in Accordance with §1.97(e); Petition Requesting Consideration of the Information Disclosure Statement; and the fee of \$130.00 as set forth in §1.17(I)(1).

- () Copies of each of the references listed on the attached Form PTO-1449 (modified) are enclosed herewith.

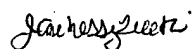
(XX) In accordance with §1.98(d), copies of some or all of the references listed on the attached Form PTO-1449 (modified) are not enclosed herewith because they were previously submitted to the U.S. Patent and Trademark Office in prior application Serial No. 10/464,310, filed June 18, 2003, for which a claim for priority under 35 U.S.C. §120 has been made in the instant application.

Please charge any deficiency or credit any overpayment to Deposit Account No. 50-1619. This form is submitted in duplicate.

() The relevance of the listed references in a foreign language is as stated in the specification at pages @@.

(XX) All listed references are in the English language.

Respectfully submitted,

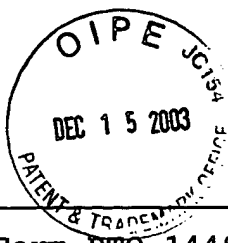


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Date: December 10, 2003

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Form PTO-1449 Modified		Docket No. DC-0232	Serial No. 10/677,673
List of Patents and Publications Cited by Applicant (Use several sheets if necessary)		Applicant Hillary D. White	
		Filing Date October 2, 2003	Group Not Yet Assigned
U.S. Department of Commerce			
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)			
	AA	Amini and Ahmadiani, "Increase in testosterone metabolism in the rat central nervous system by formalin-induced tonic pain", <i>Pharmacol. Biochem. Behav.</i> 2002 74:199-204	
	AB	Amandusson et al., "Estrogen receptor-like immunoreactivity in the medullary and spinal dorsal horn of the female rat", <i>Neurosci. Lett.</i> 1996 196:25-28	
	AC	Amandusson et al., "Colocalization of Oestrogen Receptor Immunoreactivity and Preproenkephalin mRNA Expression to Neurons in the Superficial Laminae of the Spinal and Medullary Dorsal Horn of Rats", <i>Eur. J. Neurosci.</i> 1996 8:2440-2445	
	AD	Amandusson et al., "Estrogen-induced alterations of spinal cord enkephalin gene expression", <i>Pain</i> 1999 83:243-248	
	AE	Bammann et al., "Total and free testosterone during pregnancy", <i>Am. J. Obstet. Gynecol.</i> 1980 137:293-298	
	AF	Blomqvist A., "Sex Hormones and Pain: A New Role for Brain Aromatase?", <i>Compar. Neurol.</i> 2000 423:549-551	
	AG	Burckhardt et al., "The Fibromyalgia Impact Questionnaire: Development and Validation", <i>J. Rheumatol.</i> 1991 18:728-733	
	AH	Crofford et al., "Fibromyalgia: Where Are We a Decade After the American College of Rheumatology Classification Criteria Were Developed", <i>Arthr. Rheumat.</i> 2002 46(5):1136-1138	
	AI	Dessein et al., "Hyposecretion of adrenal androgens and the relation of serum adrenal steroids, serotonin and insulin-like growth factor-1 to clinical features in women with fibromyalgia", <i>Pain</i> 1999 83:313-319	
EXAMINER		DATE CONSIDERED	

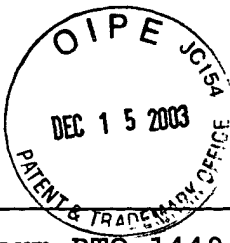


Form PTO-1449 Modified List of Patents and Publications Cited by Applicant (Use several sheets if necessary) U.S. Department of Commerce	Docket No. DC-0232	Serial No. 10/677,673
	Applicant Hillary D. White	
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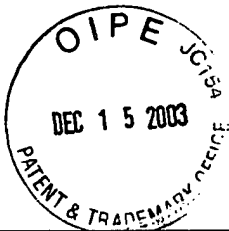
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)

	AJ	Evard et al. "Localization and Controls of Aromatase in the Quail Spinal Cord", <i>J. Compar. Neurol.</i> 2000 423:552-564
	AK	Fletcher et al., "Failure of Estrogen Plus Progestin Therapy for Prevention", <i>J. Amer. Med. Assoc.</i> 2002 288(3):366-368
	AL	Gintzler A.R., "Endorphin-Mediated Increases in Pain Threshold during Pregnancy", <i>Science</i> 1980 210(Issue 4466):193-195
	AM	Goldenberg et al., "A Randomized, Double-Blind Crossover Trial of Fluoxetine and Amitriptyline in the Treatment of Fibromyalgia", <i>Arthrit. Rheumat.</i> 1996 39(11):1852-1859
	AN	Javanbakht et al., "Pharmacokinetics of a Novel Testosterone Matrix Transdermal System in Healthy, Premenopausal Women and Women Infected with the Human Immunodeficiency Virus", <i>J. Clin. Endocrinol. Metab.</i> 2000 85(7):2395-2401
	AO	Ma et al., "Substance P and Enkephalin Immunoreactivities in Axonal Boutons Presynaptic to Physiologically Identified Dorsal Horn Neurons. An Ultrastructural Multiple-Labeling Study in the Cat", <i>Neuroscience</i> 1997 77(3):793-811
	AP	Miller et al., "Transdermal Testosterone Administration in Women with Acquired Immunodeficiency Syndrome Wasting: A Pilot Study", <i>J. Clin. Endocrinol. Metab.</i> 1998 83(8):2717-
	AQ	Okun et al., "Beneficial Effects of Testosterone Replacement for the Nonmotor Symptoms of Parkinson Disease", <i>Arch. Neurol.</i> 2002 59:1750-1753
	AR	Paiva et al., "Impaired Growth Hormone Secretion in Fibromyalgia Patients", <i>Arthr. Rheumat.</i> 2002 46(5):1344-1350

EXAMINER**DATE CONSIDERED**



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		Filing Date October 2, 2003	Group Not Yet Assigned
U.S. Department of Commerce			
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)			
	AS	Tapanainem et.al, "Effect of growth hormone administration on human ovarian function and steroidogenic gene expression in granulosa-luteal cells", <i>Fertility and Sterility</i> 58(4):726-732	
	AT	Wolfe, F. et al., "The American College of Rheumatology 1990 Criteria for the Classification of Fibromyalgia", <i>1990 Arthrit. Rheumat.</i> 33:160-172	
	AU	Baldelli et al., "Growth Hormone Secretagogues as Diagnostic Tools in Disease States", <i>Endocrine</i> 2001 14(1):95-99	
EXAMINER		DATE CONSIDERED	



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Docket No.
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10/677,673List of Patents and Publications
Cited by Applicant
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Hillary D. White

U.S. Department of Commerce

Filing Date
October 2, 2003Group
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U. S. PATENT DOCUMENTS

Examiner Initial		Document No.	Date	Name	Class	Subclass
	BA	5,935,949	8-10-99	White	514	178

FOREIGN PATENT DOCUMENTS

Examiner Initial		Document No.	Date	Country	Translation YES	NO

EXAMINER

DATE CONSIDERED